

## REMARKS

The official action of 2 February 2011 has been carefully considered and reconsideration of the application as amended is respectfully requested.

Claims 1-43 have been rewritten as new claims 44-62 and limited to the sucrose synthase of SEQ ID NO: 12, which is encoded by SEQ ID NO: 11, a method of producing a transgenic plant that overexpresses the sucrose synthase of SEQ ID NO: 12 and transgenic plants that overexpress the sucrose synthase of SEQ ID NO: 12. The claims as rewritten correspond to those allowed in the corresponding European application.

The claims as rewritten include subject matter from two (2) groups for which the Examiner required restriction as allegedly not relating to a single general inventive concept under applicable PCT unity of invention rules, namely: (a) the group (Group IV) directed to a method for production of a transgenic plant and a transgenic plant (see claims 52-61) and (b) the group (Group II) encompassing the sucrose synthase of SEQ ID NO:12 and the corresponding DNA sequence of SEQ ID NO: 11 (see claims 44-51). In Applicants' response filed 29 November 2011, Applicants elected Group IV and traversed the restriction requirement. In the official action of 2 February, the Examiner has made the restriction requirement final. Applicants respectfully request reconsideration of this requirement and reserve their right to petition from this requirement in accordance with the provisions of MPEP 818.03(c).

The basis for Applicants' request for reconsideration is that the claims as amended all recite a sucrose synthase characterized by SEQ ID NO: 12 which, as discussed below in connection with a response to the prior art rejection, is novel and nonobvious over the prior art. This being the case, there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features that define a contribution over the prior art. Accordingly, Applicants respectfully submit that the requirement for restriction should not be maintained and reconsideration of the requirement is requested. See MPEP 1850 ("Although lack of unity of invention should certainly be raised in clear cases, it should neither be raised **nor maintained** on the basis of a narrow, literal or

academic approach.” Emphasis added.).

Claims 34 and 38-43 were rejected under 35 USC 102(b) as allegedly being anticipated by Cheikh et al. Claims 34-35 and 38-43 were rejected under 35 USC 103(a) as allegedly being unpatentable over Cheikh et al in view of Baroja-Fernandez et al. Applicants respectfully traverse these rejections.

The claimed invention is based at least in part upon Applicants’ discovery of an enzyme having an affinity for ADP that is greater than the affinity shown by other enzymes known in the art (the wild type enzyme) and that is, therefore, able to produce ADPG and, consequently, starch in plant tissues in a more effective way than was known in the art. In particular, Applicants discovered an enzyme (sucrose synthase characterized by the SEQ ID NO: 12) whose affinity for ADP is greater than that observed in other enzymes (wild type enzyme) such that the production of ADPG and starch catalyzed by the sucrose synthase characterized by the SEQ ID NO: 12 is more effective than the production of ADPG and starch catalyzed by the wild type enzyme.

This is shown in the Examples in the present specification. Specifically, the Examples show that the method for producing a recombinant sucrose synthase characterized by SEQ ID NO: 12 results in an SS isoform which has an affinity for ADP much greater than the affinity described for the wild type SS extracted from plant tissues (see Example 2 of the specification as filed). As can be seen on page 25 of the specification as filed, the  $K_m$  value for ADP of the recombinant sucrose synthase characterized by SEQ ID NO: 12 of potato origin is 0.2 mM and its  $K_m$  value for sucrose in the presence of saturated concentrations of ADP is 100mM. In contrast, Table 1 of Baroja-Fernandez et al describes that the  $K_m$  value for ADP of the wild type enzyme, extracted from potato, is 0.3 mM and its  $K_m$  value for sucrose in the presence of saturated concentrations of ADP is 220mM. In other words, the  $K_m$  values of the sucrose synthase characterized by SEQ ID NO: 12 are clearly lower than the  $K_m$  values of the enzyme disclosed in Baroja-Fernandez et al. Put another way, the affinity of the sucrose synthase characterized by the SEQ ID NO: 12 for ADP is 50% greater as compared with the affinity of the wild type enzyme.

The affinity for sucrose of the sucrose synthase characterized by SEQ ID NO: 12 is 110% higher than the affinity for sucrose shown by the potato wild type. Consequently, the production of ADPG catalyzed by sucrose synthase characterized by SEQ ID NO: 12 is more effective than the production of ADPG catalyzed by the wild type enzyme. Since ADPG is the universal precursor of starch biosynthesis in plants (see specification as filed at page 1 lines 36 and 37), greater quantities of starch can be obtained when the reaction for producing ADPG is catalyzed by the sucrose synthase characterized by SEQ ID NO: 12 as compared with the quantities of starch that can be obtained when the reaction is catalyzed by the wild type enzyme.

In view of the above, Applicants respectfully submit that the amendments to the claims to recite the sucrose synthase of SEQ ID NO: 12 assures that the claimed invention is novel and nonobvious in view of the cited art. For one thing, the claimed sucrose synthase differs from that described in Baroja-Fernandez at four (4) amino acid residues. See point 2.4 of the International Preliminary Examination Report in the international stage of this application; see, also, attached charts comparing the claimed amino acid and nucleotide sequences with the wild type sequences. Accordingly, a combination of the cited references, even if proper, would not arrive at the invention defined by the claims as amended.

Moreover, there was no motivation or reason in Baroja-Fernandez et al or in the prior art as a whole to modify the wild type enzyme to obtain the isoform sucrose synthase characterized by SEQ ID NO: 12. There *a fortiori* was nothing in the prior art to show or suggest that any such modification would result in an isoform having greater affinity for ADP. In the absence of a motivation or reason to modify the references in the manner needed to arrive at the claimed invention, the references cannot set forth even a *prima facie* case of obviousness for the invention defined by the claims as amended.

The cited art also cannot set forth even a *prima facie* case of obviousness for the invention defined by the claims as amended for at least another reason: the prior art did not disclose any method for making the claimed isoform. See MPEP 2144.09(IV) (“If the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the

compound itself is in the possession of the public.”). In this respect, none of the cited references discloses the necessary tools for obtaining the isoform sucrose synthase characterized by SEQ ID NO: 12, such as primers characterized by SEQ ID NO: 5 to 10. In other words, the prior art does not describe features that are essential for obtaining the claimed sucrose synthase isoform characterized by SEQ ID NO: 12.

For the above reasons, Applicants respectfully submit that the cited art cannot set forth even a *prima facie* case of anticipation or obviousness for the invention defined by the claims as amended. Moreover, even assuming for the sake of argument that the cited art could set forth a *prima facie* case, the evidence in the specification of the unexpected properties of the claimed sucrose synthase and of the transgenic plants expressing the same (see discussion above) would be sufficient to overcome any such *prima facie* of obviousness. See MPEP 2144.09(VII) (“The presumption of obviousness based on a reference disclosing structurally similar compounds may be overcome where there is evidence showing there is no reasonable expectation of similar properties in structurally similar compounds.”).

In this respect, none of the references envisages an enzyme having an affinity for ADP greater than the affinity shown by other enzymes known in the art and, therefore, able to produce ADPG, and consequently starch, in a more effective way. Regarding the transgenic plants, none of the references shows or suggests the unexpected and inventive property of transforming plants with a vector encoding the nucleic acid of SEQ ID NO: 11 to obtain transgenic plants having higher contents of sucrose, G6P, ADPG and starch than those observed in the same tissue or organ of corresponding plants transformed with a vector comprising the sequence that encodes for the wild type SS enzyme.

The claimed invention is therefore not anticipated by or obvious over any of the prior art documents, either taken alone or in combination. Accordingly, Applicants respectfully submit that the prior art rejections of record should be withdrawn.

Claims 36 and 37 were rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the enablement requirement because they were directed to novel plasmids which were allegedly not described in the specification in a way as to enable

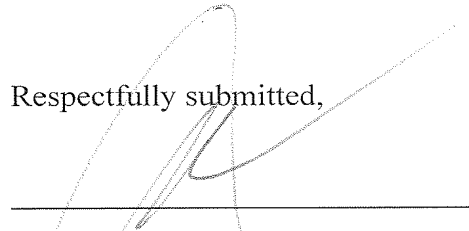
one of skill in the art to make and/or use them. These claims have been canceled and replaced with new claim 54 directed to the novel plasmid.

To overcome this rejection, Applicants advise that a suitable deposit of the subject plasmid has been made under the Budapest Treaty and submit herewith a Statement of Biological Culture Deposit that shows that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and that all applicable certifications have been met. Accordingly, Applicants respectfully submit that this rejection should be withdrawn.

In view of the above, Applicants respectfully submit that all rejections and objections of record have been overcome and that the application is now in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Please charge Account No.12-0425 for any fees which may be due by this paper.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'CLIFFORD J. MASS', is written over a horizontal line.

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